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Ms. Pamela Barclay
Deputy Director, Health Resources
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Re: Certificate of Need Task Force

Dear Ms. Barclay:

I am pleased to offer these comments to the Certificate of Need Task Force. It has been some time since the CON rules were last examined closely, and during that interval there have occurred important changes in the health care environment that warrant careful reconsideration of some of the premises underlying the current regulatory structure. I commend Chairman Salamon and the members of the Commission for recognizing the need to look again at these important questions, and for creating this forum for doing that.

I offer these thoughts as an experienced observer of, and participant in, the Maryland health care system. I serve as the President and Chief Executive Officer of LifeBridge Health, the parent organization of Sinai Hospital of Baltimore, Northwest Hospital Center, Levindale Hebrew Geriatric Center and Hospital, and Jewish Convalescent and Nursing Home, which collectively operate over 1100 hospital and nursing home beds. Prior to LifeBridge's formation in 1998, I served for eight years as the President and CEO of Sinai Hospital. Over the years, LifeBridge and its component institutions have been active participants in the CON process, and we currently have pending two certificate of need applications (one for Sinai and one for Levindale), as well as a request for exemption involving Northwest and Jewish Convalescent.

My comments relate primarily to the types of projects that should be subject to CON review, and secondarily to the process by which CON applications and requests for exemption or determination of noncoverage are reviewed and acted upon by the Commission and its staff.

General Principles

LifeBridge Health supports the fundamental idea of CON regulation. We believe that a carefully designed and efficiently-administered CON program can meaningfully improve the quality and cost-effectiveness of Maryland's health care system. At the same time, we believe that the CON review must be applied judiciously, and should be employed only when allowing the competitive market to function on its own is likely to yield outcomes that are inconsistent with public purposes. More specifically, CON review should be required only if allowing providers to act in accordance with normal market forces will unnecessarily increase costs, impair quality, or otherwise undermine the effectiveness of the statewide health care system. We encourage the Commission to examine each of the types of projects currently subject to CON review, and to ask whether, in light of these considerations, continued regulatory review is justified.

It is important to note that many of the premises once used to justify CON regulation have been proven incorrect or superseded by changed circumstances. For example –

- Historically, a major premise for the initiation of CON review was that capital expenditures by hospitals would inevitably drive up the amounts paid by patients and payors for hospital services. But in Maryland today that is clearly untrue. Under the ratesetting formulas employed by the Health Services Cost Review Commission (HSCRC), no hospital can count on recovering costs associated with capital expenditures through an increase in its payment rates. Indeed, many hospital projects require CON review even if the hospital commits not to seek rate increases to cover the associated capital costs.

- A similar situation exists for nursing homes. Nursing homes have three basic sources of revenues: individual patients ("private pay"), Medicare, and Medicaid, with Medicaid being by far the largest. Private pay rates are effectively set by the competitive market; Medicare rates are set prospectively by the federal government; and Medicaid rates are subject to rigorous spending caps. Consequently, in most cases, capital expenditures by nursing homes have only minimal (if any) mpact on the amounts they receive for their services.

- For many years it was widely assumed that, in health care, supply created its own demand – that increases in capacity produce increases in utilization. But that premise has been proven false as well. There is no credible evidence that increasing the number of hospital beds leads patients to seek hospital admission, that building more operating rooms leads more patients to request surgery, or that the availability of nursing home beds will lead the elderly to prefer institutional to home-based care.

Specific Recommendations – Scope of CON Review

Applying the above principles to specific situations, we offer the following recommendations:

Hospitals

A CON should continue to be required for the establishment of a new hospital. One of the hallmarks of the Maryland health care system is that the burdens of uncompensated and undercompensated care are spread across all hospitals. The experience of non-CON states makes clear that the establishment of new hospitals in areas that are already well-served typically results in "cream-skimming": shifting profitable procedures and patients away from existing providers, making it difficult for existing providers to continue to meet the community's needs. We must not allow this to happen in Maryland.

A CON should continue to be required for the establishment of a new, highly-specialized service, particularly open heart surgery (including angioplasty), neonatal intensive care, burn care, and major organ transplants. There is abundant evidence that, in these services, quality is tied to the attainment of certain volume levels. The establishment of new programs in geographic areas that are currently well-served will dilute the volume of existing providers, and thus potentially impair quality without any offsetting benefits.[1]

No CON should be needed for hospital capital expenditures of any size, so long as the hospital pledges not to seek a rate increase to cover the cost of the project. The combination of normal market forces and the HSCRC ratesetting system already provides a strong incentive for hospitals to spend their capital dollars efficiently. Absent any impact on hospital rates, we see no reason to require a hospital to secure a CON for capital expenditures.[2]

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[1] We have previously urged the Commission to eliminate the current CON requirement for autologous stem cell transfers. We continue to believe that such procedures are outside the scope of the CON statute, and that, for a variety of reasons I will not discuss here, they are qualitatively different from the major organ transplants that are properly subject to CON review.

[2] Staff has occasionally expressed the concern that hospitals may undertake capital expenditures beyond their financial capacities. We believe that the question of a hospital's capacity to fund capital projects is best left to the bond underwriters, banks, and others who provide the debt capital typically used to fund these projects. If they are comfortable that the debt can be repaid, we see no reason for the MHCC to second-guess that judgment.

A CON should not be required for increases in hospital bed or operating room capacity, so long as the hospital pledges not to seek a rate increase to cover project costs. Hospitals need to be able to increase their capacity to meet community needs – a fact that the General Assembly recognized when it decided to link licensed capacity to actual occupancy rates. There is absolutely no incentive for a hospital to build unnecessary beds or operating rooms. Requiring a hospital to seek CON review for these projects simply delays the hospital's ability to serve its community. In fact, the review process itself tends to increase total project costs due to the inflation associated with the six to twelve months or more that the review process typically entails.[3]

To the extent a project is subject to CON review, the current policy prohibiting construction of shell space should be dropped. The creation of shell space is a cost-effective way of planning for the future. Preventing hospitals from building shell space means that, instead of building an entire building at once, construction must be done in pieces, at a greater total cost. It means that, inevitably, roofs will have to be removed and replaced; elevators will have to be rebuilt; and operations will have to be disrupted to accommodate construction above in-use patient care areas. The current policy is not required by statute or regulation and can be readily eliminated by a change in policy.

Nursing Homes

Except in extraordinary circumstances, a CON should not be required to increase the bed capacity of an existing facility. Under current regulations, in most parts of the State, there is no possibility of securing CON approval for additional nursing home beds, so that the only way a facility can expand is by purchasing "bed rights" from existing providers. It is not clear what this policy accomplishes other than protecting the business interests of facility owners. Preventing successful nursing homes from expanding denies potential residents the ability to choose the facility that best meets their needs and preferences.[4]

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[3] We recognize that some bed or operating room expansions may be so extensive as to change the character of a facility, making them more appropriate subjects for CON review. We would not oppose requiring CON review of all projects calling for an increase of perhaps 40% or more in the number of beds or operating rooms that a facility operates. We also recognize that additional scrutiny may be required in jurisdictions that have only two or three hospitals, to prevent facilities from overbuilding in an attempt to gain a permanent competitive advantage.

[4] Again, we recognize that more extensive review may be required where a facility is seeking to increase its capacity so substantially as to constitute a fundamental change in character; a 40% increase in beds may be an appropriate threshold for such additional review.

A CON should not be required for capital expenditures by nursing homes, regardless of amount, unless those expenditures will have a material impact on the facility's per-diem Medicaid rates. As with hospitals, the combination of market forces and third-party payment rules already provide a powerful constraint on unnecessary capital expenditures. Absent a demonstrable impact on Medicaid spending, the requirement that a CON be secured for capital expenditures serves no public purpose, and simply delays investments needed to maintain physical plants or meet patient preferences.

Ambulatory Surgery

A CON should continue to be required for the establishment of a new, multi-room ambulatory surgical center. We support a CON requirement for new ambulatory surgery centers for the same reason we support such requirements for new hospitals: ASCs frequently place inequitable burdens on hospitals, by "skimming" off well-compensated procedures and well-insured patients. While hospitals have (with some support from the HSCRC) accommodated the ASC phenomenon to date, the creation of additional ASCs would put the existing equilibrium in jeopardy. We also encourage the Commission to consider whether the existing statutory exemption for one-operating room facilities has led to an undesirable proliferation of these smaller centers and should be reconsidered.

Review Process

Whatever projects are subject to regulatory review, we believe the MHCC must address the process by which CON applications, exemption requests, and determinations of noncoverage are reviewed by the Commission and its staff. I emphasize that our suggestions for improving the review process are not intended as criticism of the Commission's staff. This group of dedicated, experienced professionals has done extraordinary work in coping with a confusing and often ambiguous statutory mandate, as well as a workload that often swamps the available human and other resources. I hope that the Commission appreciates the exceptional talent that has been amassed within the staff, and does whatever it can to ensure that the staff's workload and resources are appropriately balanced.

The MHA's comments to the Task Force offer a number of helpful comments regarding the CON review process. For our part, we offer the following suggestions:

The State Health Plan should be subjected to a prompt and comprehensive review, to ensure that each standard is directly relevant to an articulable public policy goal. Too much provider, staff, and Commission time is being spent trying to assess compliance with standards whose purpose is unclear or obsolete.

If applications are being evaluated based on informal policies rather than the standards formally included in the State Health Plan, those policies should be clearly articulated and consistently applied. Providers cannot be expected to hit the target with their regulatory filings if the target is undefined, or shifts from application to application.

Completeness questions and requests for additional information should be limited to matters needed to assess compliance with applicable standards. An inordinate amount of time is spent responding to questions that seem to have no bearing on the approvability of an application. We are happy to provide Commission staff with as much information about our business as they would like, but that education should happen outside of the review process and should not be allowed to delay project review and approval.

Transfers within a merged asset system that do not cross jurisdictional boundaries should be permitted upon notice to the Commission, without formal action by the Commission. Merged asset systems such as LifeBridge are constantly asking where programs and services can be deployed most efficiently. Transfers within a merged system do not require a formal CON, but they do require that the full Commission issue a formal determination of exemption – a process that (despite a shorter regulatory deadline) can take several months. A simple notice requirement would serve the same goals and eliminate an unnecessary burden on providers and Commission staff.

The staff should be instructed to place noncontroversial applications on a fast track, with such applications deemed approved unless other action is taken by the full Commission within 90 days after docketing. The Commission currently has several dozen CON applications under review. The staff's workload makes it virtually impossible for the Commission to comply with the statutory deadlines for their review. The result is that even clearly beneficial projects are delayed pending Commission action. A "fast track" process for noncontroversial applications would allow the staff to concentrate its resources on contested applications or those that raise serious policy concerns.

Detailed analyses of pending applications should be limited to those raising serious policy concerns or for which it is essential to have a full regulatory record. It is our impression that a great deal of valuable staff time is consumed preparing lengthy, detailed recommendations for every application on which the Commission is being asked to take action, even if the application is unopposed and does not present significant legal issues. Allowing these applications to proceed on the basis of less comprehensive staff reports – a preliminary draft of which could even be prepared by the applicant – would, again, conserve limited staff resources and eliminate costly delays.

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I appreciate the opportunity to participate in this important process and to share these thoughts with you and the members of the Task Force. If you have any questions about any of these suggestions, please do not hesitate to contact me.

Sincerely yours,

Warren A. Green